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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/501,409	07/15/2004	Kenji Okada	YMOR:330	9556
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EXAMINER				
RAMILLANO, LORE JANET				
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/501,409

Applicant(s)

OKADA ET AL.

Examiner

LORE RAMILLANO

Art Unit

1797

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 4/25/08.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 20-27 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 20-27 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 7/15/04 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/CDC)
- 4) ☐ Interview Summary (PTO-413)
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____
- Paper No(s)/Mail Date _____

DETAILED ACTION

Status of Claims

1. In applicant's reply filed on 4/25/08, applicant added new claims 20-27. Claims 1-19 are cancelled. Claims 20-27 are pending and are under examination in the application.

Claim Objections

2. In light of applicant's amendments, the prior claim objection of claim 5 is withdrawn.

Claim Rejections - 35 USC § 112

3. The rejection of claims 1, 5, 7-12, and 16-18 under 35 U.S.C. 112, second paragraph, is withdrawn. In light of applicant's new amendments, new rejections follow.

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 20-27 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. In particular, the claim language, "a portion of the annular channel" in claims 20 and 24, with respect to the recited valve, does not appear to be supported by the original disclosure. Based on the figs. 7A-B of the drawings, it appears that the recited valve is not between a portion of the annular

channel since the annular channel (19) is the portion that houses the water absorbing member alone. It appears that the recited valve is between the annular channel (19) and the analysis area (7) and not a portion of the annual channel.

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 20-27 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 20 and 24 are rejected because the recited, "first hole" and "second hole," do not appear to distinctly claim the subject matter of applicant's invention. Based on the disclosure, it appears that applicant's substrates (numerals 3 and 2 of fig. 1) share a common axial hole, as indicated by numeral 4 in figure 1. Is applicant intending to claim that the "axial hole" is made of a first hole and a second hole? Furthermore, examiner suggests amending the claim language, "a first hole through a center thereof," in claims 20 and 24, to "a first hole at a center thereof," and amending "a second hole at a center thereof," to "a second hole at the center thereof."

Claims 20 and 24 are rejected because the language, "recessed into a rear surface of the upper substrate" does not appear to distinctly claim the subject matter of applicant's invention. To further clarify the reasoning for this rejection, as indicated in the prior Office action (filed on 1/25/08), it does not appear that the recited channels are recessed into the rear surface of the upper substrate since they appear to be located in the middle surface of the upper substrate and not only in the rear surface of the upper

substrate. The claim language cited above does not appear to properly claim where the channels are located with respect to the upper substrate.

Claims 20 and 24 are rejected because the claim language, "annular channel" and "outer portion (of the channel)," is indefinite. It appears that the recited outer portion of the channel comprises the annular channel based on the disclosure recited in para. [0058]-[0060] of the published application. What is the relationship between the annular channel and the outer portion of the channel?

Furthermore, the claim language, "a portion of the annular channel" is indefinite. It does not appear, based on the drawings in figs. 7A-B, that the valve is between a portion of the annular channel. It appears that the valve is between the annular channel and the analysis area.

Claims 20 and 24 are rejected because the claim language, "a channel wall" is indefinite. Based on the claim language in claims 20 and 24, it is not clear how the recited valve controls the flow of fluid in the channel if there is a wall in the channel that prevents water from flowing between the inner and outer portion of the channel. Examiner recommends including language, i.e. a channel wall having a round hole, as recited in para. [0058] in the published application to clarify this issue.

Regarding claims 20 and 24, the word "mean" is preceded by the word(s) "biasing" in an attempt to use a "means" clause to recite a claim element as a means for performing a specified function. However, since no function is specified by the word(s) preceding "means," it is impossible to determine the equivalents of the element, as

required by 35 U.S.C. 112, sixth paragraph. See *Ex parte Klumb*, 159 USPQ 694 (Bd. App. 1967).

Drawings

8. In light of applicant's claim amendments, the drawings are objected to under 37 CFR 1.83(a) because they fail to show **"valve between a portion of the annular channel"** as described in claims 20 and 24. Any structural detail that is essential for a proper understanding of the disclosed invention should be shown in the drawing. MPEP § 608.02(d). Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Prior art rejections

9. In light of applicant's amendments, the rejections over the prior art are withdrawn. New rejections follow.

Claim Rejections - 35 USC § 103

10. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

11. **Claims 20-27** are rejected under 35 U.S.C. 103(a) as being unpatentable over Krutzik et al. ("Krutzik," US 7141416) in view of Bienhaus et al. ("Bienhaus," US 5855852).

Krutzik discloses a disk-shaped upper substrate having a first hole through a center thereof, the upper substrate comprising:

a plurality of injection ports (122) cut through the upper substrate and located around the first hole in circumferentially spaced relation to each other;

plurality of water absorbing members recessed into a rear surface of the upper substrate and in a radially outer peripheral portion of the disk in circumferentially spaced relation, each of the water absorbing members comprising a porous material and containing a blood coagulating agent for coagulating a liquid specimen (i.e. col. 12, lines 16-24);

a plurality of channels recessed into a rear surface of the upper substrate, each of the channels connecting an injection port to a water absorbing member, and extending radially straight from the injection port to the water absorbing member, each of the plurality of channels comprising: a plurality of analysis areas (140, fig. 4), each

located midway in a channel and coated with a reagent for reaction with a constituent of a liquid specimen to be analyzed (i.e. figs. 13-15);

an annular channel extending circumferentially in the radially outer peripheral portion of the upper substrate, the annular channel connecting the plurality of channels and housing the water absorbing members (i.e. figs. 13, col. 5, lines 62-65); and

a lower substrate bonded with a second hole at a center thereof, the lower substrate bonded to the upper substrate, and comprising: a reflective film on a surface of the lower substrate (i.e. col. 12, lines 41-60),

wherein the analysis disk is rotatable about an axis thereof to pass a liquid specimen injected into a channel from an injection port to an analysis area and a water absorbing member. (i.e. col. 13, lines 35-52).

Krutzik further discloses the following: a portion of the channel which is radially inward of an outer end portion provided with the water absorbing member is coated with a hydrophobic material (i.e. col. 23, lines 12-45); and the optical detection means which scans the analysis area to optically detect a constituent of the liquid specimen guided through the channel toward the outer periphery of the disk by the rotation (i.e. fig. 20).

As to claims 20, 22-24, 26, and 27, while Krutzik discloses a channel wall that divides the channel into an inner portion (i.e. channels including 131, fig. 13) and an outer portion (i.e. 133, fig. 13), Krutzik does not specifically disclose having a valve between a portion of the annular channel and the analysis area; and having a valve comprising a valve body, and a biasing mean, such as a leaf spring.

Bienhaus discloses a liquid vessel comprising a ball valve system (i.e. fig. 1), which includes a spiral spring (i.e. A23, "biasing mean") that presses a sphere (i.e. A24, "valve body") against a tapered outlet opening (i.e. wall with opening in fig. 1). Bienhaus further discloses that the sphere may be made of metal, i.e. steel or plastic (i.e. nylon) and can also have an elastic coat. In figure 2, Bienhaus discloses a needle valve system, which includes a leave spring (i.e. A26, "biasing mean") that presses a needle (i.e. A25, "valve body") that seals the outlet opening (i.e. wall with opening in fig. 2).

With regard to the location of the valve between the annular channel and the analysis area, at the time of the invention, it would have been obvious to a person of ordinary skill in the art to modify Krutzik's bio-disc by incorporating a valve between the annular channel and the analysis area because it would be desirable to have a structural means to regulate the flow of the sample through the channels.

With regard to the valve assembly, at the time of the invention, it would have been obvious to a person of ordinary skill in the art to modify Krutzik's bio-disc by incorporating one of Bienhaus' valve assembly because it would be desirable to have a reliable and efficient structural component to prevent backflow of the waste fluid.

Response to Arguments

12. Applicant's arguments with respect to claims **1, 5, 7-13, and 16-18** have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

13. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LORE RAMILLANO whose telephone number is (571) 272-7420. The examiner can normally be reached on Mon. to Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on (571) 272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-7420.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR.

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For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Jill Warden/
Supervisory Patent Examiner, Art Unit 1797

Lore Ramillano
Examiner
Art Unit 1797